UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,531	03/29/2001	Eugenia Wang	UNLV 1010	3924

23579 7590 02/25/2004

PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

EXAMINER	
WHISENANT, ETHAN C	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,531	WANG, EUGENIA	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-36,38-40 and 42-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,38-40 and 42-46* is/are rejected.

7)☒ Claim(s) *35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

NON-FINAL ACTION

1. The applicant's Response (filed 05 DEC 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 34-36, 38-40 and 42-46** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> > **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 102/103

4. **Claim(s) 34, 38-40 and 42-46** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heller et al. (1997).

Claim 34 is drawn to a method for screening for genes whose expression is altered by disease, age, or exogenous agent comprising screening a sample microarray comprising genes from a library, cells or animal exposed to the disease, age or exogenous agent, wherein expression of all of the genes is under the control of the same regulatory element; and comparing the expression of the genes to expression of control genes, from a library, cells or animal not exposed to the disease, age or exogenous agent.

Heller et al. teach a method of screening for genes whose expression is altered comprising all of the limitations recited in Claim 34. Admittedly, Heller et al. does not explicitly teach that all of the genes present in their microarray are under control of the same regulatory element. However, this limitation is considered to be inherent to the teaching of Heller in that all of the genes present in their array are under the control of promoters (i.e. same regulatory element). As presently understood, all genes are under the control of a promoter. The RNA polymerase binds to the DNA and begins the synthesis at a start site within the promoter. In support of this position, the examiner directs the applicant's attention to at least page 224 of the 3rd Edition of "The Molecular Biology of the Cell," authored by Alberts et al. (1994), and published by Garland Publishing Inc., New York, New York.

Claim 38 is drawn to an embodiment of Claim 34 wherein the disease is selected from as defined group which includes bone disorders. **Claim 39** is drawn to an embodiment of Claim 38 wherein the disease is selected from as defined group which includes autoimmune disorders. **Claim 40** is drawn to an embodiment of Claim 38 wherein the cancer is selected from as defined group.

Heller et al. teach these limitation in that they use DNA microarrays to study gene expression patterns in inflammatory disease (i.e. rheumatoid arthritis). Heller et al. do not explicitly teach all of disorders listed in Claim 38-40. However, as all of the disorders recited were well known at the time of the invention, it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to analyze the gene expression patterns of those genes present on the microarray taught by Heller et al. affected by the disorders recited in Claim 38-40. The ordinary artisan would have been motivated to analyze the gene expression patterns of those disorders in the method of Heller et al. in order

to identify previously unrecognized alterations in the expression of specific genes which would have provided leads for further investigation. Also, note the motivation to utilize this method explicitly provided by Heller et al. in the last line of their abstract. "These results successfully demonstrate the use of the cDNA microarray system as a general approach for dissecting human diseases.

Claim 42 is drawn to an embodiment of Claim 34 wherein the exogenous agent is a drug or toxin. **Claim 43** is drawn to an embodiment of Claim 34 wherein the library is derived from cells or tissues treated with one or more compounds *in vitro*.

Heller et al. teach this limitation in that they use LPS and PMA to activate the monocyte cell line (i.e. *in vitro*) MM-6 in order to monitor changes in gene expression upon activation with these compounds (i.e. drugs or toxins). See, at least, for example, p.2153, 1st column, lines 1-24.

Claim 44 is drawn to an embodiment of Claim 34 wherein the library is derived from cells obtained from an individual of a particular age, having a particular disease or disorder, or derived from the neurological system, the cardiovascular system, the musculoskeletal system, or cancerous tissues.

Heller et al. teach this limitation in that they use cDNA from cells obtained from an individual having a particular disease or disorder (i.e. from a person with rheumatoid arthritis).

Claim 45 is drawn to an embodiment of Claim 34 wherein the exogenous agent is selected from the group consisting of proteins or peptides, sugars or polysaccharides, nucleic acid molecules, and synthetic molecules.

Heller et al. teach this limitation in that they use LPS as the exogenous agent. Please note that LPS is a polysaccharide.

Claim 46 is drawn to an embodiment of Claim 43 wherein the exogenous agent is selected from the group consisting of proteins or peptides, sugars or polysaccharides, nucleic acid molecules, and synthetic molecules.

Heller et al. teach this limitation in that they use LPS as the exogenous agent. Please note that LPS is a polysaccharide.

5. **Claim(s) 34, 38-40, 42-46** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeRisi et al. (1996).

Claim 34 is drawn to a method for screening for genes whose expression is altered by disease, age, or exogenous agent comprising screening a sample microarray comprising genes from a library, cells or animal exposed to the disease, age or exogenous agent, wherein expression of all of the genes is under the control of the same regulatory element; and comparing the expression of the genes to expression of control genes, from a library, cells or animal not exposed to the disease, age or exogenous agent.

DeRisi et al. teach a method of screening for genes whose expression is altered comprising all of the limitations recited in Claim 34. Admittedly, DeRisi et al. does not explicitly teach that all of the genes present in their microarray are under control of the same regulatory element. However, this limitation is considered to be inherent to the teaching of DeRisi in that all of the genes present in their array are under the control of promoters (i.e. same regulatory element). As presently understood, all genes are under the control of a promoter. The RNA polymerase binds to the DNA and begins the synthesis of mRNA at a start site within the promoter. In support of this position, the examiner directs the applicant's attention to at least page 224 of the 3rd Edition of "The Molecular Biology of the Cell," authored by Alberts et al. (1994) Published by Garland Publishing Inc., New York, New York.

Claim 38 is drawn to an embodiment of Claim 34 wherein the disease is selected from as defined group which includes bone disorders. **Claim 39** is drawn to an embodiment of Claim 38 wherein the disease is selected from as defined group which includes autoimmune disorders. **Claim 40** is drawn to an embodiment of Claim 38 wherein the cancer is selected from as defined group.

DeRisi et al. teach these limitation in that they use DNA microarrays to study gene expression patterns in human cancer. DeRisi et al. do not explicitly teach all of disorders listed in Claim 38-40. However, as all of the disorders recited were well known at the time of the invention, it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to analyze the gene expression patterns of those genes present on the microarray taught by DeRisi et al. affected by the disorders recited in Claim 38-40. The ordinary artisan would have been motivated to analyze the gene expression patterns of those disorders in the method of DeRisi et al. in order to identify "previously unrecognized alterations in the expression of specific genes which would have provided leads for further investigation" (see the last line of the abstract of DeRisi et al.).

Claim 42 is drawn to an embodiment of Claim 34 wherein the exogenous agent is a drug or toxin. **Claim 43** is drawn to an embodiment of Claim 34 wherein the library is derived from cells or tissues treated with one or more compounds *in vitro*.

DeRisi et al. teach this limitation in that they teach introducing a normal human chromosome 6 (i.e. drugs or toxins) into the human melanoma cell line, UACC-903 *in vitro* . See, at least, for example, p.457, 1st column.

Claim 44 is drawn to an embodiment of Claim 34 wherein the library is derived from cells obtained from an individual of a particular age, having a particular disease or disorder, or derived from the neurological system, the cardiovascular system, the musculoskeletal system, or cancerous tissues.

DeRisi et al. teach this limitation in that they use cDNA from cells obtained from an individual having a particular disease or disorder (i.e. from human melanoma cell line, UACC-903).

Claim 45 is drawn to an embodiment of Claim 34 wherein the exogenous agent is selected from the group consisting of proteins or peptides, sugars or polysaccharides, nucleic acid molecules, and synthetic molecules.

DeRisi et al. teach this limitation in that they use a normal human chromosome 6 (i.e. a nucleic acid molecule) as the exogenous agent.

Claim 46 is drawn to an embodiment of Claim 43 wherein the exogenous agent is selected from the group consisting of proteins or peptides, sugars or polysaccharides, nucleic acid molecules, and synthetic molecules.

DeRisi et al. teach this limitation in that they use a normal human chromosome 6 (i.e. a nucleic acid molecule) as the exogenous agent.

CLAIM OBJECTIONS

6. **Claim(s) 35-36** are objected to because they are dependent upon a rejected independent base claim.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

7. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

CONCLUSION

8. **Claim(s) 34-40 and 42-46** is/are rejected and/or objected to for the reason(s) set forth above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT
PRIMARY EXAMINER

Art Unit 1634